IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	10/501,026
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First-Named Inventor:	Robert D. Coleman
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Examiner:	HELEN MEI-PING CHUI
GROUP ART UNIT:	1616
Attorney Docket No.:	94-10400
Title:	FUNGICIDE COMPOSITIONS

DECLARATION OF DR. ROBERT D. COLEMAN UNDER 37 C.F.R. § 1.132

I, Robert D. Coleman, hereby state as follows:

1. I received a Master of Science degree in Public Health from the University of Oklahoma Medical Center (Oklahoma City). I subsequently attended the University of Texas, Graduate School of Biomedical Science at M.D. Anderson Hospital and Tumor Institute, Houston, Texas, where I received a Ph.D. in the area of biochemistry. I then obtained post-doctoral training in molecular biology and genetics at Pennsylvania State University Medical Center (Hershey, PA) and chemical mutagenesis at Cornell University (Ithaca, NY).

2. My Professional Experience is summarized as follows:

- Summerdale, Inc., Founder, Verona, WI (current)
- Auxein Corp., Co-founder & Director of Product Development, Lansing, MI
- Michigan Biotechnology Institute, Process Engineering, Senior Scientist, Lansing

- Argonne National Laboratory, Energy & Engineering Systems, Section Leader, Chicago
- CPC International, Biotechnology/Molecular Biology Division, Group Leader, Chicago

- I was the Director of Product Development at and co-founder of Auxein Corporation and led the field development trials on fruits and vegetables, developed a major portion of the intellectual property, obtained early financing for the company and conducted necessary trials for the product chemistry section to obtain EPA registration for the company's 1st product (AuxiGro). In 2001, Auxein merged with Mycotech to form Emerald Bio-Agriculture, Inc (Lansing, MI).
- Prior to joining Auxein Corporation, I was a senior scientist at MBI International (formerly Michigan Biotechnology Institute) and was responsible for the production, analysis and development of organic acids as plant growth enhancers.
- I was a section leader at Argonne National Laboratory and led the development of technologies relating to: a) lactic acid production and b) synthesis of degradable, poly-lactic acid (PLA) and modified PLA films and coatings, including coatings for urea-based fertilizer micro-spheres and sustained release of plant growth enhancers from PLA films. Patent applications were filed for novel, enhanced use characteristics for PLA including UV and water sensitivity. The technology resulted in multiple licensing agreements and several R&D collaborations.
- Selected patents and publications relating to work performed at Argonne, MBI International and Auxein Corporation and only those references pertaining to: 1) the production and use of natural organic acids for agricultural products and, 2) studies in the area of pesticides and microbes are given below.

Selected patents:

- Bonsignore, P. V. and R. D. Coleman. Water and UV Degradable Lactic Acid Polymers.

- U. S. Patent 5,360,892, November 1, 1994.
- Bonsignore, P. V. and R. D. Coleman. Water and UV Degradable Lactic Acid Polymers. U. S. Patent 5,563,238, October 8, 1996.
- Coleman, R. D. Plasmids Containing a Gene Coding from a Thermostable Pullulanase and Pullulanase-Producing Strains of *E. coli* and *B. subtilis* Containing the Plasmids. U. S. Patent 4,612,287, September 16, 1986.
- Coleman, R. D. Enhanced Herbicides. U. S. Patent 6,218,336, April 17, 2001.
- Coleman, R. D. Enhanced Herbicides. U. S. Patent 6,509,297, January 21, 2003.
- Coleman, R. D. Enhanced Herbicides. U. S. Patent 6,812,190, November 2, 2004.
- Coleman, R. D. Enhanced Herbicides. U. S. Patent 6,969,696, November 29, 2005.
- Coleman, R. D. Enhanced Herbicides. Chinese Patent, issued 2006.
- Coleman, R. D. Fungicide Compositions. Published/Patent Pending.
- Coleman, R. D. Pesticide Compositions and Methods for Their Use. A continuation-in-part of Fungicide Compositions. Application has been published by the USPTO.
- Kinnersley, A., R. D. Coleman and E. Tolbert. Method for Stimulating Plant Growth Using GABA. U. S. Patent 5,604,177, February 18, 1997.
- Kinnersley, A., R. D. Coleman, C.-Y. Kinnersley and J. L. McIntyre. Method for Increasing Fertilizer Efficiency. U.S. Patent 5,840,656, November 24, 1998.
- Tsai, S.-P., S. H. Moon, and R. D. Coleman. Fermentation and Recovery Process for Lactic Acid Production. U. S. Patent 5,464,760, November 7, 1995.

Selected, peer-reviewed publications and book chapters:

- Coleman, R., Dunst, R. and C. Hill. 1980. A Double Base Change in Alternate Base Pairs Induced by Ultraviolet Irradiation in a Glycine Transfer RNA Gene. Molecular and General Genetics. 177: 213 – 222.
- Dunst, R., Coleman, R., Harnish, B. and C. Hill. 1981. A System for Measuring the Frequencies of Tandem and Non-Tandem Double Base Substitutions Induced by Ultraviolet Irradiation. Molecular and General Genetics. 184: 445 – 449.

- Coleman, R., Yang, S. and M. McAlister. 1987. Cloning of the Debranching Enzyme Gene from *Thermoanaerobium brockii* into *Bacillus subtilis*. Journal of Bacteriology. 169: 4302 – 4307.
- Yang, S. and R. Coleman. 1987. Detection of Pullulanase in Polyacrylamide Gels Using Pullulan-Reactive Red Agar Plates. Analytical Biochemistry. 160:480–482.
- Coleman, R. D. 1993. Degradable Plastics in Polymers Section (p. 332-338), for *McGraw Hill Yearbook of Science and Technology*, McGraw-Hill, Inc., NY.
- Coleman, R. 1993. Cloning of Genes Involved in Carbohydrate Utilization in *Thermoanaerobium brockii*. In: Genetics and Molecular Biology of Anaerobes (Editor: M. Sebald). Chapter 47. Springer Verlag, NY.
- Kakar, S. N., J. Bumpus, and R. D. Coleman. 1993. Fungal Degradation of Organophosphorous Insecticides. Applied Biochemistry and Biotechnology, 39/40:715-725.
- Tsai, S., Coleman, R. Moon, S., Schneider, K. and C. Sanville-Millard. 1993. Strain Screening and Development for Industrial Lactic Acid Fermentation. Applied Biochemistry and Biotechnology. 39/40:323-335.
- Coleman, R. and D. Penner. 2006. Desiccant Activity of Short Chain Fatty Acids. Weed Technology. 20: 410 – 415.
- Coleman, R. and D. Penner. 2008. Organic Acid Enhancement of Pelargonic Acid. Weed Technology. 22:38 – 41.

3. I have reviewed the current application with pending claims and the outstanding office action dated June 10, 2009, in the above referenced case along with the cited references, which has been incorporated by reference into the current outstanding office action. My conclusions are summarized below.

4. The current patent application referenced above, for which I am the inventor, discloses the discovery of a composition comprising a fatty acid (having from 5 to 22 carbons) and an organic carboxylic acid (or salt thereof) which is different from the fatty acid, a carrier and at least one emulsifier, wherein the composition is capable of forming an emulsion upon mixing with water. Applicant's combination of the two different carboxylic

acids, one of which is a fatty acid, has substantially greater efficacy than either component alone and/or their additive efficacy. The combination's efficacy is further enhanced by the addition of an emulsifier.

5. I understand that the current pending claims 1, 3-4, 15, 17-18, 20 and 25 have been denied based upon the opinion of the Examiner that as of the priority filing date of the application, it would have been obvious to one of ordinary skill in the art to carry out the claimed invention, with an expectation of success based on Tate (W.O. 91/13552) in view of Puritch et al. (U.S. Patent No. 5,106,410). Similarly and for the same reasons, claims 1-6, 10-12, and 15-25 stand rejected based on Sedum et al. (U.S. Patent No. 5,246,716) in view of Bar-Shalom (U.S. Patent No. 5,143,718) and further in view of Puritch et al. (U.S. Patent No. 5,106,410). Based on my education and experience in this field, I find that the suggested combinations would either not be expected to provide the result suggested by the Examiner; one skilled in the art would not have made the suggested combination based on the teaching of the references, and that the discovery of a synergistic effect for the combination of a fatty acid and a second carboxylic acid different from the fatty acid was surprising and unexpected.

6. The suggested combination of an organic acid (Tate) and a fatty acid (Puritch et al.) would not be expected to provide a composition having fungicidal properties. Tate teaches that the organic acid in his formulation serves to promote spore germination and fungal growth. Puritch et al. teaches a composition in the form of an aqueous emulsion of a fatty acid that exhibits herbicidal properties. When applied to a plant, the Puritch et al. formulations exhibit phytotoxic properties. According to Tate, the organic acid component would be expected to promote fungal growth resulting in plant damage. According to Puritch et al., an aqueous emulsion of a fatty acid would exhibit phytotoxic properties, stunting or killing a treated plant. Neither of these references would lead one skilled in the art to expect a composition containing an organic acid and a fatty acid to exhibit superior fungicidal properties.

7. The combination of Sedum et al. in view of Bar-Shalom, further in view of Puritch et al. is postulated to make obvious the claimed combination containing a fatty acid, a

carboxylic acid that is different from the fatty acid, a carrier, and an emulsifier where the composition is capable of forming an emulsion upon mixing with water.

Sedum et al. Sedum et al. teaches a fungicidal composition based on a relatively insoluble fatty acid salt. Sedum et al. teaches: (a) that the soluble anion of the fatty acid exhibits herbicidal properties, and (b) that increasing the concentration of the soluble anion of the fatty acid increases the composition's phytotoxicity.

Bar-Shalom The Bar-Shalom reference teaches a composition containing aluminum chloride, an aluminum salt of at least one organic acid. The formulations are effective as antiperspirants and may be effective in the treatment of Athletes Foot, a fungal infection. Organic acids are cited as having various biological properties, including at least 13 specific examples followed by etc. The list of 13 includes antifungal properties. The Bar-Shalom's compositions are taught to be anhydrous or substantially anhydrous to be effective as antiperspirants and as antifungal agents.

Puritch et al. As noted in the discussion of Tate and Puritch et al. (paragraph 6, above), the composition taught by Puritch et al. is an aqueous emulsion containing a fatty acid. The emulsion is reported to have herbicidal properties.

8. According to the Examiner, "It would have been obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Sedum et al. with Shalom, B.D. and Puritch et al. to arrive at the instant invention." In order to reach this conclusion, one skilled in the art would have to ignore the following derived from the cited references:

(a) Adding a second carboxylic acid (from Bar Shalom) to the fatty acid salt (Sedum et al.) as suggested by the Examiner would, based on the cited reference, be expected to increase the concentration of the soluble anion of the fatty acid, increase the composition's phytotoxicity, and make the combination unsatisfactory for use as a plant fungicide.

(b) Bar-Shalom teaches that both the antiperspirant and antifungal activity would be compromised in an aqueous formulation. As a result, the reference teaches away from a

formulation that would include more than trace amounts of water. An aqueous emulsion of a fatty acid would contain more than a trace of water and be expected to have an adverse effect on the proposed antifungal properties.

(c) Puritch et al. teaches that an aqueous emulsion containing a fatty acid is phytotoxic and exhibits herbicidal properties. As a result, an aqueous formulation containing a fatty acid, regardless of any additional components, would not be viewed as being suitable for use as a plant fungicide.

9. Commercial fungicides derived from petroleum sources typically have:

- Lengthy periods of registration (several years) and very expensive registration costs (tens to hundreds of millions of dollars for state and federal approvals),
- High chronic toxicity; i.e., as suspected carcinogens, teratogens and/or mutagens and
- Issues of pathogen resistance.

Moreover, many of the current commercial fungicides will likely require replacement because their continued registration under the Food Quality Protection Act (FQPA) will render them highly restricted or cancelled. Hence, interest by the crop protection industry is very high for safer, effective alternatives to the current commercial fungicides for use in conventional as well as organic agriculture. Registration of natural products via the BioPesticide route in the USEPA generally requires less than $100,000 and can be done in less than one year. The search for a safer natural fungicide has been ongoing for many years.

10. To date, very few natural fungicides are available. Because of low performance (such as bio-control fungicides), pathogen resistance (i.e., strobilurins) and/or in general, higher cost, natural fungicides are often not competitive with synthetic or petrochemical-based fungicides. Such "natural fungicides" have typically proven inadequate compared to competing commercial products derived from petrochemicals. As noted in the present application, low molecular weight fatty acids such as caprylic acid (C8) has low levels of fungicidal properties. Caprylic acid is a generally nontoxic ubiquitous compound found in plant and animal fats (coconut and palm seed oil, human breast milk, etc.). Unfortunately,

fungicide activity of C8 used alone (although slightly effective in laboratory and greenhouse trials) is too low to be practical in field applications. Therefore, formulations containing fatty acids such as C8 alone is not an option for growers in agricultural production; i.e., a fatty acid, alone, would not have sufficient potency for adequate control of crop pathogens.

11. However, the surprising and unexpected finding disclosed in the current application that the addition of an organic acid different from the fatty acid (such as glycolic acid) to a fatty acid formulation greatly enhances fungicide activity now provides a highly important option in crop protection for growers seeking a safer alternative to the current commercial fungicides. Substantial documentation is provided in the current application, especially for fruit crops (multi-year field trials at Michigan State University), where fatty/organic acid formulations are either comparable to or superior to commercial, synthetic fungicides, most of which are known to be chronic toxins. Some of the existing commercial fungicide products have already been eliminated or are under major restrictions by the FQPA. Safer, replacements are currently being sought by the crop protection industry. A licensee is currently prepared to commercialize a formulation containing a fatty acid, an organic carboxylic acid, different from the fatty acid, a carrier and an emulsifier. This invention will now permit wide-scale use of a "safe and natural" fungicide for not only growers but also other end-users such as the home consumer.

12 It is my opinion that a safe and natural fungicide based on a fatty acid has been needed for several years, but hasn't become available until now. Had the claimed combination of a fatty acid with a carboxylic acid different from the fatty acid, along with a carrier and an emulsifier been obvious based on the cited references, such a formulation would already have been commercially available. It has not.

13. It is further my opinion that: (1) one skilled in the art would not have any motivation to make the cited combinations; (2) that the combination, if made, would have been expected to be harmful to any plants treated with the combination, and (3) that the combination providing superior fungicidal properties, if made, could

only result using hindsight. Further nothing in the cited references would lead one skilled in the relevant art to expect the documented superior performance of my combination including a fatty acid, a carboxylic acid different from the fatty acid and an emulsifier.

14. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on that information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by a fine or imprisonment, or both, under §1001 of Title XIIX of the United States Code and that such willful false statements may jeopardize the validity of the application and/or patent issued therefrom.

Date: July 20 2009 Robert D. Coleman

Robert D. Coleman Ph.D.